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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,165	06/19/2003	Charles Quentin Davis	100390-10050	9727

22852 7590 06/13/2007  
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
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WASHINGTON, DC 20001-4413

EXAMINER
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WRIGHT, PATRICIA KATHRYN

ART UNIT	PAPER NUMBER
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1743

MAIL DATE	DELIVERY MODE
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06/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/600,165	<b>Applicant(s)</b> DAVIS ET AL.	
	<b>Examiner</b> P. Kathryn Wright	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) 1-31 and 44-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-43 and 78-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/2004;9/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 and 71, drawn to an apparatus and method for retaining a plate, classified in class 422, subclass 104.
  - II. Claims 2-13 and 72-76, drawn to an apparatus and method for positioning a plate with plate loader, classified in class 422, subclass 65.
  - III. Claims 14-18 and 77, drawn to a device and method for detecting proper alignment of a plate, classified in class 271, subclass 226.
  - IV. Claims 19-31, drawn to an apparatus and method for training a probe to locate and aspirate reagents, classified in class 422, subclass 100.
  - V. Claims 32-43 and 78-80, drawn to a fluid handling device and method of using, classified in class 436, subclass 180.
  - VI. Claims 44-57 and 81-84, drawn to an apparatus and method for detecting the presence/absence of a reagent in a container, classified in class 422, subclass 106.
  - VII. Claims 58-60 and 85, drawn to a positive displacement pump with three-way valve and method of using, classified in class 137, subclass 151.
  - VIII. Claims 61-65 and 86, drawn to a positive displacement pump and method of using, classified in class 137, subclass 147.
  - IX. Claims 66-70 and 87, drawn to a positive displacement pump with piston, classified in class 137, subclass 148.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the first and second positioning blocks having a plurality of retaining ledges required in group I. The subcombination has separate utility such as device for aligning any planar object, such as bank notes.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

3. Inventions [I, II] and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination of group III has separate utility such as a wafer alignment detection system, like that taught in US patent pub. No. 2004/0179190. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

4. Inventions [I,II,II] and [IV,V, VI, VII, IX] are directed for use in an assay system. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, function, or effect. Specifically, the training probe feature of

group IV is not required in groups I-III. Likewise, the reagent manifold feature of group V; the light source and detector features of group VI, the three-way valve feature of the positive displacement pump of group VII, the cleanout plug feature of the positive displacement pump of group VIII, and the gas sediment trap features of group IX are not required in any of the other groups. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5. Inventions [IV,V, VI, VII, IX] are directed for use in an assay system. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, function, or effect. Specifically, the training probe feature of group IV is not required in any of the other groups. Likewise the reagent manifold feature of group V is not required in any of the other groups. The light source and detector features of group VI is not required by the other groups. The three-way valve feature of the positive displacement pump of group VII and the cleanout plug feature of the positive displacement pump of group VIII and the gas, sediment trap of group IX are not required in any of the other groups. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

6. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Rebecca McNeill on June 4, 2007 a provisional election was made with traverse to prosecute the invention of group V, claims 32-43 and 78-80. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-31, 44-77 and 81-87 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Specification***

9. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the limitation "wherein the aspiration chamber diameter is 25% larger than the probe diameter" in original claim 42. This limitation does not find antecedent basis in the specification.

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

11. Applicant is reminded of the proper language and format for an abstract of the disclosure. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.

12. The disclosure is objected to because of the following informalities: the "Brief Description of the Drawings" section does not include a description of each figure. Applicant should reference each figure individually and avoid using ellipsis (e.g., 3a-2,...3a-10).

Appropriate correction is required.

### ***Drawings***

13. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "groove for mounting the seal" (claims 38 and 39) and the "face seal" (claim 79) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

14. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "425" has been used to designate both the "fluid handling manifold" (see for example page 35, line 12) and "fluid handling station body" (see for example page 45, lines 19).



15. The drawings are further objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "400" and "471" have both been used to designate the "fluid handling station". See for example page 16, line 2 and page 45, line 7. Similarly, reference characters "405" and "150" have both been used to designate the "probe".

16. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "400" at page 45.

17. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 432, 433, 437, 438 (see for example Fig. 4c). Furthermore, applicant alternatively refers to the "gas input lines" and the "air input lines". It is hereby respectfully requested that applicant amend the specification (including the claims) choosing one of the phrases for consistency and clarity.

18. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

19. Claims 32-43 are objected to because of the following informalities: the preamble of claim 32 currently recites "a fluid handling device". The specification discloses a "fluid handling station" at page 44. The body of the claim sets forth a combination of two components (reagent manifold and a movable probe). Therefore, the Examiner suggests the preamble be amended to recite a fluid handling system or fluid handling station for aspirating reagents, rather than a "device" to correspond with the specification.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

20. Claims 34-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 32 recites both a "probe sealing surface" and a "reagent manifold

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sealing surface". Claims 33-37 includes an additional third seal configured to enclose the access port to form a face seal when the probe is lowered into the aspiration chamber. The specification (including Figs. 4A-B) does support a sealing surface 410 on the probe 405 and a sealing surface 415 on the aspiration chamber. However, no other seal is described in the specification. Thus, the specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

21. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

22. Claims 32-43 and 78-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32 and 78 both recite "the aspiration chamber being defined within the reagent manifold". Based on the construction of the claim, the aspiration chamber, plurality of reagent input lines, gas input and reagent manifold have been interpreted by the Examiner as elements which comprise the "reagent manifold". Thus, it confusing and indefinite as to what applicant means by the limitation "the aspiration chamber being defined within the reagent manifold". Clarification respectfully requested.

Claim 32 is also rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See

MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship between the reagent manifold sealing surface and the aspiration chamber. Is the sealing surface disposed on the chamber?

As discussed above, claim 32 recites a “probe sealing surface” and a “reagent manifold sealing surface”, however claims 33-37 are confusing and indefinite since these claim appears to be an additional third seal not shown in the figures or disclosed in the specification. For the purposes of examination, the seal in claim 34 will be treated as the “probe sealing surface”. However, clarification of the claims is required.

Claim 42 recites the aspiration chamber diameter is 25% larger than the probe diameter; however neither the chamber or probe have been defined as cylindrical. Furthermore, the inner and outer dimension of each element should be referred to. Clarification is requested.

Claim 43 recites “the aspiration chamber and the probe each having a respective height, the aspiration chamber height being substantially the same as the probe height”. It is unclear from where the heights of the aspiration chamber and probe are being measured. Furthermore, the specification lacks some standard for measuring the heights intended.

Claims 78–80 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship between the gas input line and the aspiration chamber.

Claim 79, recites the sealing is accomplished through a face seal. This step is confusing and indefinite since it is not clear what applicant means by a "face seal".

***Claim Rejections - 35 USC § 102***

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 32-41, 43 and 78-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Buzza et al. (US Patent no. 4,888,998), hereinafter "Buzza".

Buzza teaches a fluid handling station for aspirating reagents. Specifically, the station includes a fluid manifold having an aspiration chamber 54 with an access port, see Fig. 2. The aspiration chamber includes a plurality of fluid input lines 84, 86, 87, 88 each in selective fluid communication with the aspiration chamber via independently controlled valves 96, 100, 110, 116. The aspiration station also includes a manifold sealing surface 60 and a movable probe 22 having a probe tip and a probe sealing surface 62, wherein the probe sealing surface engages the manifold sealing surface when the probe is lowered into the aspiration chamber, see col. 3, line 55- col. 4, line 40 and Fig. 2 of Buzza.

Please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., supply reagent or gas) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all

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the structural limitations of the claim. (Emphasis added.) *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

It is the position of the Office that fluid supply lines 84, 88 could be used to supply gas and the supply lines 86 and 87 could be used to supply reagent, such that the gas input lines are arranged on the aspiration chamber above the plurality of reagent input lines, relative to the bottom surface of the chamber. Moreover, Buzza teaches a plurality of reagent sources may be used (see for example col. 5, lines 60-66.)

With respect to the method steps recited in claim 78-80, Buzza teaches moving the probe having a probe tip and a probe sealing surface into a reagent manifold, sealing the probe against the reagent manifold, and aspirating fluid from the fluid input lines after activation of a fluid line valve to fill the chamber with fluid (see col. 5, lines 22+.)

### ***Claim Rejections - 35 USC § 103***

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

26. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

27. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buzza (US Patent no. 4,888,998).

The teachings of Buzza have been set forth previously, *supra*. Buzza does not explicitly state the aspiration chamber 54 has an inner dimension 25 percent larger than the outer dimension of the probe. However, it would have been an obvious matter of design choice to one having ordinary skill in the art at the time of the claimed invention to have made the inner dimension of the aspiration chamber 54 at least 25 percent larger than the outer dimension of the probe so that the probe is not damaged during insertion into the chamber. Furthermore, it has been held that a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

### ***Double Patenting***

28. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

29. Claims 32-43 and 77-80 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 65-66 of copending Application No. 10/841,569 (corresponding to US Patent Pub. No. 2005/0250173). Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention as presently claimed is fully encompassed by the invention claimed in the co-pending application '569.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

30. No claims allowed.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.




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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 11, 2007

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